

## SpiderFX™ Embolic Protection Device

510(k) Number: K063785

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR §807.92.

### General Provisions:

Submitter's Name

ev3  
9600 54<sup>th</sup> Avenue North  
Plymouth, MN 55442

JAN 19 2007

Official Contact:

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Trade Name:

SpiderFX™ Embolic Protection Device

Common Name/Usual Name:

Embolic Protection Device

Classification Name:

Catheter, Percutaneous

Class:

Class II, 21 CFR 870.1250

### Predicate Device:

SpideRX™ Embolic Protection Device (K062201)

### Device Description:

The SpiderFX™ Embolic Protection Device is a percutaneously delivered distal embolic protection system that can be delivered over any 0.014" or 0.018" guidewire. The SpiderFX Embolic Protection Device contains a Capture Wire composed of a nitinol mesh filter mounted on a 190 cm or a convertible 320/190 cm PTFE-coated 0.014" stainless steel guidewire and a dual-ended SpiderFX Catheter for delivery and recovery.

**Intended Use:**

The SpiderFX™ Embolic Protection Device is indicated for use as an embolic protection system to contain and remove embolic material (thrombus/debris). The device also acts as the guidewire while performing percutaneous transluminal coronary angioplasty or stenting procedures in coronary saphenous vein bypass grafts with reference vessel diameters of 3.0 to 6.0 mm. The safety and effectiveness of this device as an embolic protection system has not been established in the cerebral or peripheral vasculature.

**Summary of Technological Characteristics:**

The SpiderFX™ Embolic Protection Device is a rapid exchange distal embolic protection device that is compatible with 0.014"/0.018" primary guidewires and utilizes a nitinol mesh filter to capture debris. The SpiderFX Device is substantially equivalent to the SpiderRX™ Embolic Protection Device (K062201) with several modifications, including the addition of a 23 gauge blunt tip needle and a rapid exchange length (190 cm) Capture Wire, and modifications to the radiopaque mouth marker, flexible connector, and marking of the primary wire exit port.

**Summary of Testing:**

Non-clinical verification and validation of the SpiderFX™ Embolic Protection Device consisted of *in vitro* bench testing, package integrity testing, and *in vivo* animal studies. Test results verified that the SpiderFX Device is equivalent to the predicate device and is adequate for its intended use.

**Statement of Equivalence:**

The SpiderFX™ Embolic Protection Device is substantially equivalent to the currently marketed SpiderRX™ Embolic Protection Device (K062201) in intended use, materials, technological characteristics and performance.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ev3, Inc.  
c/o Mr. David Worrell  
Manager, Regulatory Affairs  
9600 54<sup>th</sup> Avenue North  
Plymouth, MN 55442-2111

JAN 19 2007

Re: K063785  
SpiderFX™ Embolic Protection Device  
Regulation Number: 21 CFR 870.1250  
Regulation Name: Percutaneous catheter  
Regulatory Class: II (two)  
Product Code: NFA  
Dated: December 19, 2006  
Received: December 21, 2006

Dear Mr. Worrell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Bram D. Zuckerman, M.D.  
Director

Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications For Use

510(k) Number (if known): K063785

Device Name: SpiderFX™ Embolic Protection Device

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Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE  
IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Duma R. Vachney  
(Division Sign-Off)  
Division of Cardiovascular Devices

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Confidential

Device Number K063785

ev3 Inc.